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10 IN THE UNITED STATES DISTRICT COURT
11 FOR THE EASTERN DISTRICT OF CALIFORNIA

13 **ASSOCIATION FOR ACCESSIBLE
14 MEDICINES,**

2:20-cv-01708-TLN-DB

15 Plaintiff,

16 v.

**[REDACTED] DEFENDANT'S
OPPOSITION TO PLAINTIFF'S
MOTION FOR SUMMARY JUDGMENT
AND TO CONVERT PRELIMINARY
INJUNCTION INTO PERMANENT
INJUNCTION**

17 **ROB BONTA, IN HIS OFFICIAL
18 CAPACITY AS ATTORNEY GENERAL
19 OF THE STATE OF CALIFORNIA,**

Date: February 8, 2024
Time: 2:00 p.m.
Courtroom: 2
Judge: The Honorable Troy L. Nunley
Action Filed: 8/25/2020

20 Defendant.

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INTRODUCTION

2 Facing evidence that “pay-for-delay” settlement agreements cost consumers
3 approximately \$3.5 billion per year, the California Legislature enacted Assembly Bill 824 (“AB
4 824”) to shield the State’s residents from these increased costs. *See* Dkt. No. 68-3 (“Attorney
5 General RJN”), Ex. A at 8; *see also* Robin C. Feldman & Prianka Misra, *The Fatal Attraction of*
6 *Pay-for-Delay*, 18 Chi.-Kent J. Intell. Prop. 249, 256 (2019) (estimating a \$12 billion “transfer . . .
7 . from consumers to producers” from pay-for-delay settlement agreements). AB 824’s purpose is
8 to “preserve[] consumer access to affordable drugs” through regulation of these anticompetitive
9 agreements. Attorney General RJN, Ex. A at 7. It does so by establishing a rebuttable
10 presumption that pay-for-delay settlement agreements are anticompetitive and, if the presumption
11 is not rebutted, makes such agreements unlawful. Cal. Health & Safety Code § 134002(a)(1).
12 Reflecting that the Legislature’s concern was harm to California consumers, a violation of AB
13 824 can only occur “in connection with the sale of a pharmaceutical product” in California. *Id.*;
14 *see also* Attorney General RJN, Ex. A at 12 (AB 824 “applies regardless of the location of the
15 business, as long as California consumers are affected.”).

16 Plaintiff Association of Accessible Medications (“AAM”) has challenged AB 824 on
17 Commerce Clause, Excessive Fines, Due Process, and preemption grounds. This Court
18 previously determined that AAM had sufficiently demonstrated injury-in-fact and traceability for
19 associational standing. *See* Dkt. No. 42 (“PI Order”) 6-8. Although it ultimately rejected AAM’s
20 Excessive Fines, Due Process, and preemption claims (*see* Dkt. No. 47 (“Modif. Order”) at 8-13),
21 this Court agreed with AAM that AB 824 violated the dormant Commerce Clause (PI Order at
22 15). With the exception of pay-for-delay agreements negotiated, executed, or entered in
23 California, the Court preliminarily enjoined enforcement of AB 824. Modif. Order at 8.

24 AAM now seeks entry of summary judgment in its favor as well as the conversion of the
25 preliminary injunction into a permanent injunction. *See* Dkt. No. 75 (“AAM MSJ”).
26 Unfortunately for AAM, the facts and the law have changed since this Court granted AAM’s
27 preliminary injunction request, and those changes wholly undermine AAM’s claims.

1 First, evidence that AAM itself submitted in support of its summary judgment motion
 2 reveals that AAM can no longer demonstrate that it is entitled to associational standing. That
 3 evidence shows [REDACTED]
 4 [REDACTED] and therefore are not entitled to the injunctive relief AAM seeks. The
 5 individualized inquiry necessary to determine each AAM member's entitlement to the relief
 6 sought undermines AAM's claim to associational standing. *See Hunt v. Wash. State Apple*
 7 *Advertising Comm'n*, 432 U.S. 333, 343 (1977).

8 Second, the Supreme Court's recent decision in *National Pork Producers Council v. Ross*,
 9 598 U.S. 356 (2023), precludes AAM's dormant Commerce Clause claim. AAM relied
 10 exclusively on *Healy v. Beer Institute*, 49 U.S. 324 (1989), *Brown-Forman Distillers Corp. v.*
 11 *New York State Liquor Authority*, 476 U.S. 573 (1989), and *Baldwin v. G.A.F. Seeling, Inc.*, 249
 12 U.S. 511 (1935) (collectively the "Baldwin-Healy line") to argue that AB 824 inappropriately
 13 regulated out-of-state conduct, regardless of the in-state effects from that conduct. *See* Dkt. No.
 14 15-1 ("Inj. Mot.") at 9; *see also* Dkt. No. 1 ("Compl.") ¶¶ 80-81. This Court, in turn, looked to
 15 the Baldwin-Healy line when preliminarily enjoining enforcement of AB 824. *See* PI Order at
 16 11-12.

17 In *National Pork Producers*, however, the unanimous Court held that the dormant
 18 Commerce Clause does not "per se" invalidate States' laws based solely on their effects on out-
 19 of-state conduct. 598 U.S. at 374. In so holding, the Court concluded that the Baldwin-Healy
 20 line applied only to discriminatory or protectionist "price control or price affirmation statutes"
 21 that tie[] 'the price of . . . in-state products to out-of-state prices.'" *Id.* (quoting *Pharm. Rsch. &*
 22 *Mfrs. Of Am. V. Walsh*, 538 U.S. 644, 669 (2003)).

23 Nor can AAM avoid *National Pork Producers* by arguing that AB 824 is a "direct
 24 regulation" of out-of-state conduct. *See* AAM MSJ at 10-11. As the statute's text makes clear,
 25 AB 824 does not "directly regulate[] out-of-state transactions by those with *no* connection to the
 26 State." *National Pork Producers*, 598 U.S. at 376 n.1. The statute instead reaches out-of-state
 27 conduct only to the extent that such conduct has in-state effects. *See* Cal. Health & Safety Code
 28

1 134002(a)(1). In that, AB 824 is just the latest example of the long tradition of States shielding
 2 their residents from harmful conduct beyond their borders.

3 In light of these factual and legal changes, AAM cannot succeed on its summary judgment
 4 motion or its motion to convert the preliminary injunction into a permanent injunction.
 5 Accordingly, the Court should reject both requests.

6 **FACTUAL BACKGROUND**

7 In “pay-for-delay” or “reverse” settlement agreements, branded pharmaceutical companies
 8 pay generic manufacturers to delay offering competing products. PI Order at 2-3. Because
 9 generics are virtually always cheaper than branded alternatives, pay-for-delay agreements prevent
 10 (or at least, postpone) competition in the pharmaceutical market, which in turn results in
 11 significantly higher drug costs for consumers. *See* Feldman & Misra, 18 Chi.-Kent J. Intell. Prop.
 12 at 256. One recent study estimated that “typical consumers might pay 1,400% more for drugs
 13 that would otherwise face generic competition but for reverse settlements.” Rocco Screni,
 14 *Batten Down the Hatch[es]! Restoring the Pat. Sys.’s Role Within the Pharm. Indus.*, 70 Case W.
 15 Res. L. Rev. 821, 848 (2020). Another study revealed that between 2006 and 2017, “the cost of
 16 pay-for-delay settlements on the U.S. population ranged from \$6.2 billion to \$37.1 billion per
 17 year based on list price, and \$619 million per year to \$2.9 billion per year based on patient out-of-
 18 pocket costs.” Robin Feldman, *The Price Tag of “Pay-For-Delay*, 23 Colum. Sci. & Tech. L.
 19 Rev. 1, 32 (2022); *see also* Feldman, 18 Chi.-Kent J. Intell. Prop. at 256 (“one-year delay in
 20 generic entry represented a transfer of \$12 billion from consumers to producers”).

21 With AB 824, the California Legislature sought to protect California residents from the
 22 harm of pay-for-delay settlements. It did so by creating a rebuttable presumption of anti-
 23 competitiveness under California law for agreements satisfying three criteria: (1) that the
 24 agreement is a settlement; (2) that it is between two pharmaceutical companies; and (3) that the
 25 agreement consists of a brand-name compensating a rival generic to delay California sales of its
 26 competing drug for a period of time. Cal. Health & Safety Code §§ 134002(a)(1), 134002(e)(2).
 27 To rebut the presumption, a company can show that (1) the value received by the company is
 28 “fair and reasonable compensation”; (2) the agreement has directly generated procompetitive

1 benefits, and the procompetitive benefits of the agreement outweigh the anticompetitive effects of
2 the agreement; or (3) any other recognized antitrust defense. *Id.* § 134002(a)(3)(A)-(B).

3 A violation of AB 824 can result only in civil penalties. *Id.* § 134002(e)(1)(A)-(B).
4 Under AB 824, the civil penalty is calculated as (1) “an amount up to three times the value” given
5 or received by a party to the agreement that is “reasonably attributable to the violation of this
6 section,” or (2) “twenty million dollars (\$20,000,000), whichever is greater.” *Id.* §
7 134002(e)(1)(A)(i)-(ii). “California’s share of the market for the brand drug at issue in the
8 agreement” is AB 824’s method for determining the amount “reasonably attributable” to a
9 violation. *Id.* § 134002(e)(1)(A)(iii).

10 **PROCEDURAL BACKGROUND**

11 AAM alleges four claims in its complaint against the Attorney General of California
12 (named in his official capacity): that AB 824 1) violated the dormant Commerce Clause by
13 applying extraterritorially; 2) was preempted by federal law; 3) violated the Eighth Amendment’s
14 Excessive Fines Clause; and 4) violated due process.¹ Compl. ¶¶ 79-128. In its December 9,
15 2021 order granting AAM’s request for a preliminary injunction, the Court held that AAM had
16 established sufficient injury-in-fact for standing and enjoined any enforcement of AB 824 on
17 Commerce Clause grounds. PI Order at 8, 10-11, 15, 18. In so holding, the Court determined
18 that AB 824 theoretically could apply to settlements without “any connection with California”
19 and, relying on *Healy*, 49 U.S. at 336, concluded that AB 824 amounted to a “per se” violation of
20 the dormant Commerce Clause. PI Order at 10-11, 15.

21 On February 15, 2022, the Court granted in part and denied in part the Attorney General’s
22 request to modify the injunction. Modif. Order at 8. The Court agreed with the Attorney
23 General’s request that the injunction should not apply to settlements negotiated, executed, or

24 _____
25 ¹ In a prior challenge to AB 824, AAM alleged five claims: that 1) that AB 824 violated
26 the dormant Commerce Clause by applying extraterritorially; 2) that federal law preempted AB
27 824; 3) that AB 824 violated the Excessive Fines clause; 4) that AB 824 violated due process; and
28 5) that enforcement of AB 824 violated 42 U.S.C. § 1983. *See Ass’n for Accessible Med. v.*
Becerra, No. 2:19-cv-2281 (E.D. Cal Nov. 12, 2019) (“Case 2:19-cv-2281”). This Court denied
AAM’s preliminary injunction request in that case. Case 2:19-cv-2281, Dkt. No. 29 at 1. On
appeal, the Ninth Circuit held that AAM did not have standing and remanded with instructions for
this Court to dismiss on jurisdictional grounds. Case 2:19-cv-2281, Dkt. Nos. 46, 47, 48.

1 entered in California. *Id.* The Court held that AAM was unlikely to succeed on its preemption,
2 Excessive Fines clause, and due process claims as alternative grounds for upholding the original
3 injunction. *Id.* at 8-13. The Court rejected the Attorney General’s request to modify the
4 injunction to allow enforcement of AB 824 to out-of-state agreements covering sales in
5 California, holding that “the dormant Commerce Clause precludes the application of a state
6 statute to commerce that takes place wholly outside of the State’s borders, whether or not the
7 commerce has effects within the State.” *Id.* at 7-8 (quoting *Healy*, 491 U.S. at 336) (quotation
8 marks omitted).

9 On September 15, 2023, AAM and the Attorney General both filed motions for summary
10 judgment, and AAM additionally requested that the Court convert the preliminary injunction into
11 a permanent injunction. *See* Dkt. No. 68 (“Attorney General MSJ”); AAM MSJ.

12 **LEGAL STANDARD**

13 Moving parties are entitled to summary judgment only if they demonstrate both the absence
14 of a genuine issue as to any material fact and entitlement to judgment as a matter of law. *See* Fed.
15 R. Civ. P. 56(a). Where the moving party’s legal theory is not cognizable, summary judgment is
16 inappropriate, even if no genuine dispute of material fact exists. *See City of Oakland v. BP PLC*,
17 969 F.3d 895, 910 (9th Cir. 2020) (“[S]ummary judgment is appropriate only if the ‘movant is
18 entitled to judgment as a matter of law.’”) (quoting Fed. R. Civ. P. 56(a)).

19 **ARGUMENT**

20 The Court should deny AAM’s request for summary judgment and to convert the
21 preliminary injunction into a permanent injunction. AAM is not entitled to judgment as a matter
22 of law for two reasons.

23 First, as AAM’s own evidence reveals, the participation of each of AAM’s members is
24 necessary to establish entitlement to the injunctive relief that AAM seeks. As a result, AAM has
25 not satisfied the requirements for associational standing.

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27

28

1 Second, AAM’s dormant Commerce Clause claim is meritless.² Properly interpreted, AB
2 824 is materially indistinguishable from Proposition 12, the statute at issue in the Supreme
3 Court’s *National Pork Producers* decision. Like Proposition 12, AB 824 regulates out-of-state
4 conduct only to the extent that such conduct impacts California residents. In *National Pork*
5 *Producers*, the Supreme Court held that States can enact that form of regulation without violating
6 the dormant Commerce Clause.

7 **I. AAM’S OWN EVIDENCE SHOWS IT DOES NOT HAVE STANDING**

8 For associational standing, AAM must demonstrate that “neither the claim asserted nor the
9 relief requested requires the participation of individual members in the lawsuit.” *Hunt*, 432 U.S.
10 at 343. The evidence that AAM presented in support of its summary judgment request only
11 underscores that AAM cannot satisfy that requirement.

12 To support its standing arguments, [REDACTED]

13 [REDACTED]
14 [REDACTED] *See* Decl. of Alexandra I. Russell in
15 Support of Plaintiff’s Motion for Summ. Judg. (“Russell Decl.”), ¶¶ 7-9, Exs. F-H. [REDACTED]

16 [REDACTED] *See*
17 Russell Decl., Exs. F, H [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED] *See* Attorney General’s RJD, Ex. B; *see also* Russell Decl., Ex. H [REDACTED]
21 [REDACTED].

22 ² As the Court has already found (*see* Modif. Order at 8-13) and as the Attorney General
23 pointed out in his summary judgment motion, AAM’s preemption, Excessive Fines, and due
24 process claims are wholly meritless (Attorney General MSJ at 15-19). Notably AAM largely did
25 not discuss those claims in its motion for summary judgment, other than noting only in a footnote
26 that “as a formal matter” AAM asked “the Court to enter judgment on all of AAM’s claims.”
27 AAM MSJ at 10 n.2. Such a footnote is insufficient to demonstrate AAM is entitled to summary
28 judgment on those claims. *See Coleman v. Brown*, 922 F. Supp. 2d 1004, 1024 (E.D. Cal. 2013)
([D]efendants relegated this argument to a mere footnote and failed to provide any legal analysis
in support of their contention . . . It is thereby waived.”); *cf. Momox-Caselis v. Donohue*, 987 F.3d
835, 842 (9th Cir. 2021) (“[A] cursory mention of an issue in a footnote without citation to legal
authority is insufficient for purposes of appellate consideration.”). The Attorney General is
entitled to summary judgment in his favor on AAM’s preemption, Excessive Fines, and due
process claims.

1 This evidence reveals that the Court must undertake individualized inquiries to determine
2 whether AAM's members are entitled to injunctive relief. As the Court held in its order
3 modifying the injunction, AAM and its members are not entitled to injunctive relief with regards
4 to settlements "negotiated, completed, or entered into within California's borders." Modif. Order
5 at 8. [REDACTED]

6 [REDACTED]
7 [REDACTED] Attorney General's RJN, Ex. B; Russell
8 Decl., Exs. F-H. As the Attorney General pointed out in his summary judgment brief, three other
9 AAM members likely also are not entitled to the injunctive relief AAM seeks. Attorney General
10 MSJ at 6. [REDACTED] *See Sep.*

11 Stmt. of Undisputed Facts, at ¶¶ 1-3; Affidavit of Erica Connolly ISO Pl. Mot. for Summ. J.
12 ("Connolly Aff.") ¶¶ 2-5, Exs. A, B, C, D, E; Attorney General's RJN, Ex. C. AAM members
13 Antheia, Inc. and Amphastar Pharmaceuticals have their principal places of business in
14 California. *See Sep.* Stmt. of Undisputed Facts, at ¶¶ 1, 5-6; Connolly Aff. ¶¶ 2-3, Exs. A, B, C;
15 Attorney General's RJN, Exs. D, E.

16 Determinations about whether any of AAM's other members are entitled to the injunctive
17 relief AAM seeks would require the Court to evaluate each settlement to determine whether the
18 agreement was "negotiated, completed, or entered into within California's borders." That degree
19 of individualized inquiry is incompatible with associational standing. *See Kan. Health Care*
20 *Ass'n v. Kan. Dep't of Soc. & Rehab. Servs.*, 958 F.2d 1018, 1022-23 (10th Cir. 1992)
21 (associational standing inappropriate where court would need to "examine evidence particular to
22 individual providers"); *Rent Stabilization Ass'n of City of New York v. Dinkins*, 5 F.3d 591, 597
23 (2d Cir. 1993) (associational standing not appropriate in takings case because "it is impossible to
24 discern the identity of the aggrieved parties without delving into individual circumstances").

25 Accordingly, the Court should hold that AAM does not have associational standing and
26 therefore is not entitled to summary judgment or the conversion of the preliminary injunction into
27 a permanent injunction.

1 **II. AB 824 DOES NOT VIOLATE THE COMMERCE CLAUSE**

2 In granting AAM’s request for a preliminary injunction, the Court concluded that only
 3 AAM’s dormant Commerce Clause claim had any merit. PI Order at 15; Modif. Order at 8-13.
 4 In support of that claim, AAM argued that AB 824 violated the dormant Commerce Clause
 5 because the statute “has the practical effect of regulating commerce occurring wholly outside the
 6 State’s borders” (Compl. at ¶¶ 80-81 (quoting *Healy*, 491 U.S. at 336)), regardless whether the
 7 “settlement ‘has effects within the State’” (Inj. Mot. at 10 (quoting *Healy*, 491 U.S. at 336)).
 8 *National Pork Producers*, however, renders AAM’s arguments meritless.

9 **A. *National Pork Producers* Undercuts AAM’s Sole Commerce Clause Theory**

10 In *National Pork Producers*, the Supreme Court curtailed the *Baldwin-Healy* line of cases
 11 on which AAM relied to argue that any regulation of out-of-state conduct ran afoul of the
 12 dormant Commerce Clause. *See, e.g.*, Inj. Mot. at 8-10; Compl. ¶¶ 80, 83; *see also* PI Order at 10
 13 n.4 (“The Court agrees with the State that Plaintiff alleges that AB 824 unlawfully regulates
 14 extraterritorial activity . . . Plaintiff does not argue any other theory in its briefing.”). The
 15 unanimous *National Pork Producers* Court instead held that the *Baldwin-Healy* line addressed
 16 only the “familiar concern with preventing purposeful discrimination against out-of-state
 17 economic interests.” 598 U.S. at 371; *see also* Attorney General MSJ at 7-9 (explaining the full
 18 impact of *National Pork Producers* on AAM’s dormant Commerce Clause claim). AAM has
 19 never alleged that AB 824 discriminates against out-of-state economic interests—nor could it
 20 given that AB 824 applies to both in-state and out-of-state agreements, so long as the agreements
 21 occurred in connection with a California sale. *See* Cal. Health & Safety Code §§ 134002(a)(1);
 22 Attorney General RJN, Ex. A at 12 (AB 824 “applies regardless of the location of the business, as
 23 long as California consumers are affected.”).

24 AAM implicitly acknowledges the impact of *National Pork Producers*, arguing that AB
 25 824 is instead a “direct” extraterritorial regulation. AAM MSJ at 10 (“[T]he fundamental
 26 Commerce Clause problem with AB 824 is that, by its terms, it applies to—and *directly*
 27 regulates—settlements ‘even if the[y] w[ere] completed entirely out of state...’”). AAM no
 28 doubt pivots to this argument due to a footnote in *National Pork Producers*, in which the

1 Supreme Court refused to rule out the possibility that state statutes that “directly regulated out-of-
 2 state transactions by those with *no* connection to the State” offend the dormant Commerce
 3 Clause. 598 U.S. 356, 376 n.1; AAM MSJ at 11.

4 AB 824, however, does not offend that direct-regulation principle. Indeed, it is materially
 5 indistinguishable from Proposition 12, the statute at issue in *National Pork Producers*.
 6 Proposition 12 prohibited “the in-state sale” of pork from pigs confined in a manner that did not
 7 comply with the statute’s standards. *National Pork Producers*, 598 U.S. at 365-66. AB 824
 8 imposes materially the same form of regulation: under California statutory interpretation canons,
 9 the statute prohibits settlement agreements only if those agreements are “in connection with the
 10 sale of a pharmaceutical product” in California. *See Sullivan v. Oracle Corp.*, 51 Cal. 4th 1191,
 11 1207 (2011); *Kopp v. Fair Pol. Pracs. Comm’n*, 11 Cal. 4th 607, 643 (1995); *see also* Attorney
 12 General MSJ at 9-13 (providing additional legal context supporting interpretation of AB 824). In
 13 other words, like Proposition 12, AB 824 addresses only out-of-state conduct with in-state
 14 impacts.³ Under the Supreme Court’s clarification of the dormant Commerce Clause’s scope, AB
 15 824, like Proposition 12, is constitutionally permissible. *National Pork Producers*, 598 U.S. at
 16 376.

17 Like the *National Pork Producers* plaintiffs, AAM’s members have the choice to carve out
 18 the California market from agreements that would otherwise violate AB 824 and enter into
 19 compliant agreements for sales into the State. *See National Pork Producers*, 598 U.S. at 384
 20 (plurality opinion) (plaintiffs have choice to comply with the law, “segregate their operations,” or
 21 “withdraw from” California’s market). AAM is not entitled, however, to use the dormant
 22 Commerce Clause to impose its preference for a “particular structure of metho[d] of operation.”
 23 *Id.* That is just what AAM seeks with this case to do.

24 _____
 25 ³ Nor does AAM’s attempt to distinguish *National Pork Producers* based on the different
 26 structures of Proposition 12 and AB 824 have any merit. *See* AAM MSJ at 10-11. The Supreme
 27 Court’s reasoning turned on the fact that States have long had in place laws that have significant
 28 out-of-state effects. Those laws are constitutionally permissible so long as there is sufficient
 connection with the State. *See National Pork Producers*, 598 U.S. at 374-75, 376. As explained
 below, the harm to California residents from pay-for-delay agreements is more than sufficient
 grounds for the State to regulate out-of-state pay-for-delay agreements that are connected to in-
 state sales.

1 Because *National Pork Producers* rejected the reasoning on which AAM relies for its
 2 dormant Commerce Clause claim, the Court should reject AAM’s request for summary judgment
 3 and to convert the preliminary injunction into permanent injunction.

4 **B. AB 824 Does Not Offend Any Remaining Limits on “Direct” Regulation of
 5 Out-Of-State Conduct**

6 AAM claims that *Sam Francis Foundation v. Christies, Inc.*, 784 F.3d 1320 (9th Cir. 2015),
 7 and *Daniels Sharpsmart, Inc. v. Smith*, 889 F.3d 608 (9th Cir. 2018), nevertheless dictate the
 8 outcome in this case. AAM’s reliance on these cases is misplaced.

9 As an initial matter, *Sam Francis* and *Sharpsmart* may no longer be good law following
 10 *National Pork Producers*. Both cases relied significantly on the *Baldwin-Healy* line of cases to
 11 reach their respective results. *See Sharpsmart*, 889 F.3d at 614-15 (citing *Healy* to explain that
 12 underlying case “deal[t] with the direct regulation emanation”); *Sam Francis*, 784 F.3d at 1324
 13 (because “*Healy* governs,” statute that did not discriminate violated dormant Commerce Clause).

14 Even if *Sam Francis* and *Sharpsmart* remain good law, the Ninth Circuit has explained that
 15 so long as a State’s “ties to [the subject of regulation]” are “sufficiently strong to justify its
 16 assertion of regulatory authority,” there is no violation of the principle applied in *Sam Francis*
 17 and *Sharpsmart*. *Ward v. United Airlines, Inc.*, 986 F.3d 1234, 1240 (9th Cir. 2021) (citing *Sam*
 18 *Francis*, 784 F.3d at 1323). “[T]he analysis required under the dormant Commerce Clause
 19 largely tracks the analysis that would be required under the Fourteenth Amendment’s Due
 20 Process Clause.” *Id.* The Due Process Clause, in turn, requires only sufficient “state interests” to
 21 make application of the State’s law “neither arbitrary nor fundamentally unfair.” *Phillips*
 22 *Petroleum Co. v. Shutts*, 472 U.S. 797, 818 (1985) (quotations, citations omitted); *see also*
 23 *Strassheim v. Daily*, 221 U.S. 280, 285 (1911) (“Acts done outside a jurisdiction, but intended to
 24 produce and producing detrimental effects within it, justify a state in punishing the cause of the
 25 harm as if he had been present at the effect, if the state should succeed in getting him within its
 26 power.”).

27 California has sufficient interests in the pay-for-delay agreements that AB 824 prohibits to
 28 satisfy this standard. The purpose of AB 824 is to protect California residents from the impact of

1 increased drug prices resulting from these anticompetitive agreements. *See* Attorney General
 2 RJN, Ex. A at 7 (goal of AB 824 is to “preserve[] consumer access to affordable drugs by
 3 prohibiting brand name and generic drug manufacturers from entering into these of [sic]
 4 agreements and [making] them presumptively anticompetitive”); *id.*, Ex. A at 12 (AB 824 applies
 5 “as long as California consumers are affected”). As described above, several studies show the
 6 significant consumer harm that results from pay-for-delay agreements. *See supra* p.3. From
 7 potentially paying 1,400% more for drugs that do not face generic competition to spending \$619
 8 million to \$2.9 billion per year in extra out-of-pocket costs, the consequences of pay-for-delay
 9 settlement agreements is the substantial transfer of capital to producers from consumers—in
 10 particular, California consumers, who reside in the largest market in the country. *See* Screni, 70
 11 Case W. Res. L. Rev. at 848; Feldman, 23 Columb. Sci. & Tech. L. Rev. at 32; Feldman & Misra,
 12 18 Chi.-Kent J. Intell. Prop. at 256.

13 The true “direct regulation” cases mentioned by the *National Pork Producers* Court or cited
 14 by AAM are easily distinguishable because those cases involved laws with no (or virtually no)
 15 connection with the regulating state, thereby making their ties to the subject of regulation too
 16 weak to withstand constitutional scrutiny. In *Edgar v. Mite*, 457 U.S. 624 (1982), for example,
 17 where a plurality of the Supreme Court identified direct extraterritorial regulation, Illinois sought
 18 to “directly regulate[] out-of-state transactions by those with *no* connection to the State.”
 19 *National Pork*, 598 U.S. at 376 n.1. Specifically, *Edgar* involved an Illinois securities statute that
 20 “directly regulat[ed] transactions which [took] place ... wholly outside” of Illinois—tender offers
 21 made by out-of-state buyers to “those living in other States and having *no connection* with
 22 Illinois.” 457 U.S. at 641, 642 (plurality) (emphasis added). Illinois made no claim that these
 23 wholly out-of-state transactions had any material effect (negative or otherwise) on its residents.
 24 457 U.S. at 644.

25 In *Shutts*, the Supreme Court applied the Due Process Clause to bar the application of
 26 Kansas law to certain out-of-state activities with “no apparent connection” to Kansas. 472 U.S. at
 27 815. In so holding, the Court observed that, although the Due Process Clause prevents States
 28 from “abrogat[ing] the rights of parties beyond its borders having *no relation* to anything done or

1 to be done within them,” where States have sufficient “state interests” to avoid application of
 2 their laws being “arbitrary or unfair,” application of their laws does not offend the Due Process
 3 clause (or the dormant Commerce Clause). *Id.* at 821-22 (emphasis added) (quotations, citations
 4 omitted); *see also Ward*, 986 F.3d at 1240 (recognizing that any direct-extraterritorial-regulation
 5 inquiry under the dormant Commerce Clause tracks the due process standard applied in *Shutts*).

6 Similarly, in *Sam Francis* and *Sharpsmart*, the Ninth Circuit invalidated laws that it held
 7 had no in-state effects that would establish a sufficiently strong “tie” between the State and the
 8 underlying subject of regulation. For example, in *Sharpsmart*, the Ninth Circuit held that a
 9 California statute, which required that medical waste generated in-state had to be incinerated,
 10 even if the disposal process occurred out-of-state, had no “effect whatsoever in California.” 889
 11 F.3d at 613, 616. And, in *Sam Francis*, the Ninth Circuit held that the underlying statute required
 12 a “seller of fine art to pay the artist a five percent royalty if ‘the seller resides in California,’”
 13 even for “sales [with] *no necessary connection* with the state other than the residency of the
 14 seller.” 784 F.3d at 1322, 1323. The Court held, in other words, that “residency of the seller
 15 alone was an insufficient nexus to support regulation of out-of-state art sales.” *Ward*, 986 F.3d at
 16 1240 (discussing *Sam Francis*). In so holding, however, the Court “impl[ied] that a stronger
 17 connection could justify regulation.” *Id.*

18 AB 824 has that stronger connection. It prohibits pay-for-delay agreements only to the
 19 extent that they have a connection to pharmaceutical sales within California. *See Cal. Health &*
 20 *Safety Code §§ 134002(a)(1); Sullivan*, 51 Cal. 4th at 1207; *Kopp*, 11 Cal. 4th at 643. Because
 21 those in-state pharmaceutical sales seriously harm California consumers, California is well-within
 22 its rights to regulate “[a]cts done outside a jurisdiction, but intended to produce and producing
 23 detrimental effects within it.”⁴ *Strassheim*, 221 U.S. at 285.

24 ⁴ *AAM v. Frosh*, 887 F.3d 664 (4th Cir. 2017), is also not to the contrary. *See AAM MSJ*
 25 at 11 n.3. The *National Pork Producers* Court cited *Frosh* merely because the *Frosh* court agreed
 26 that the *Baldwin-Healy* line “address[ed] ‘price control or price affirmation statutes’ that tied ‘the
 27 price of . . . in-state products to out-of-state prices.’” 598 U.S. at 374. In *Frosh*, the Fourth
 28 Circuit held a Maryland statute violated the dormant Commerce Clause because it was
 “effectively a price control statute that instructs manufacturers and wholesale distributors as to
 the prices they are permitted to charge in transactions that do not take place in Maryland.” 887
 F.3d at 672 (emphasis added); *see also id.* at 673 (“The ‘practical effect’ of the Act, much like the

1 **C. AAM’s Interpretation of the Dormant Commerce Clause Contradicts a**
 2 **Long Tradition of State Regulation of Conduct with In-State Effects**

3 AAM’s dormant Commerce Clause arguments run counter to a century of precedents
 4 upholding States’ power to regulate out-of-state conduct with in-state effects. As the Attorney
 5 General explained in his summary judgment motion, States have long regulated beyond their
 6 borders to protect their residents from unfair competition and antitrust misconduct. Attorney
 7 General MSJ at 13-15; *see, e.g., Knevelbaard Dairies v. Kraft Foods, Inc.*, 232 F.3d 979, 993-94
 8 (9th Cir. 2000). And courts have consistently held that those regulations are constitutionally
 9 permissible. *See* Attorney General MSJ at 13-15.⁵

10 Unfair competition and antitrust misconduct are just one example, however, of States’
 11 constitutionally permissible regulation of cross-border conduct. In *Ileto v. Glock*, the Ninth
 12 Circuit upheld the application of California’s negligence and public nuisance claims against out-
 13 of-state gun manufacturers and distributors. 349 F.3d 1191, 1217 (9th Cir. 2003). The Ninth
 14 Circuit rejected the defendants’ arguments that the plaintiffs’ claims, if applied to the defendants,
 15 would violate the dormant Commerce Clause. *Id.* The Court reasoned that California’s “interest
 16 in protecting the health and safety of its residents is clearly legitimate” and was not outweighed
 17 by a potential damages award against the defendants. *Id.*

18 Likewise, in *Ward*, the Ninth Circuit rejected a dormant Commerce Clause challenge to the
 19 application of California’s Labor Code to pilots and flight attendants who worked the majority of
 20 their time outside of the State. 986 F.3d at 1241. There, the airline defendant argued that because
 21 pilots’ and flight attendants’ work primarily occurred on flights outside of California’s borders,
 22 application of the State’s Labor Code would be a “direct regulation of interstate commerce” and
 23 effect of the statutes struck down in *Brown-Forman* and *Healy*, is to *specify the price* at which
 24 goods may be sold beyond Maryland’s borders.”) (emphasis added). AB 824, unlike the statute at
 25 issue in *Frosh*, is not a “price control statute”; it operates in materially the same way as
 26 Proposition 12. *See supra* p.9. And therefore, like Proposition 12, AB 824 does not violate the
 27 dormant Commerce Clause. *National Pork Producers*, 598 U.S. at 371.

28 ⁵ Indeed, even if there were not cases rejecting dormant Commerce Clause challenges to
 29 such longstanding state laws, the historical tradition of such enactments would counsel strongly
 30 against invalidating AB 824 on the grounds pressed by AAM. As the Attorney General has
 31 explained, “[w]hen faced with a dispute about the Constitution’s meaning or application, ‘[l]ong
 32 settled and established practice is a consideration of great weight.’” Attorney General MSJ at 15
 33 (quoting *Houston Cnty. Coll. Sys. v. Wilson*, 142 S. Ct. 1253, 1259 (2022)).

1 thereby offend the dormant Commerce Clause. *Id.* at 1240. The Ninth Circuit disagreed, holding
2 that, when pilots and flight attendants are “based for work purposes in California” and “perform
3 at least some work” in the State, “California’s ties to the employment relationship are sufficiently
4 strong to justify application” of its Labor Code. *Id.* at 1241.

5 And, for decades, courts in California and elsewhere have determined that application of
6 the State’s law to out-of-state conduct with in-state effects is appropriate. For example, the
7 California Supreme Court applied the State’s prohibition on recording phone calls without all
8 parties’ consent to out-of-state companies making calls into the State. *Kearney v. Salomon Smith*
9 *Barney, Inc.*, 39 Cal. 4th 95, 106-07, 128 (2006) (application of California law to Georgia-based
10 company did not violate dormant Commerce Clause). The California Supreme Court similarly
11 applied California’s negligence laws to an out-of-state company for serving alcohol to a driver
12 who had an accident within the State’s borders. *Bernhard v. Harrah’s Club*, 16 Cal. 3d 313, 322-
13 23 (1976) (overruled on other grounds by statute) (California law applied to Nevada hotel that
14 provided driver with alcohol and driver caused accident in California). And the California
15 Supreme Court indicated that the State’s product liability laws most likely applied to out-of-state
16 manufacturers for in-state harm. *See Buckeye Boiler Co. v. Super. Ct.*, 71 Cal. 2d 893, 906 (1969)
17 (California product liability law likely to apply to Ohio manufacturer who made tank that
18 exploded in California).

19 As the Supreme Court observed in *National Pork Producers*, “[i]n our interconnected
20 national marketplace, many (maybe most) state laws have the ‘practical effect of controlling’
21 extraterritorial behavior,” a state of affairs true since the Nation’s founding. 598 U.S. at 374-75.
22 States’ “[e]nvironmental laws, . . . libel laws, securities requirements, charitable registration
23 requirements, franchise laws, [and] tort laws” all address out-of-state or cross-state conduct with
24 substantial in-state effects. *Id.* at 374-75 (quoting Jack Goldsmith & Alan Sykes, *The Internet*
25 and the Dormant Commerce Clause, 110 Yale L.J. 785, 804 (2001)). Those are nonetheless
26 constitutional exercises of States’ powers.

27
28

1 AAM's argument ignores this long history. AAM instead seeks to limit California law to
2 misconduct occurring within its borders, no matter the effect on the State's residents from out-of-
3 state misconduct. This Court should reject AAM's invitation.

4 **CONCLUSION**

5 AAM's own evidence reveals that it cannot satisfy the requirements for associational
6 standing, and on that ground alone, the Court should deny AAM's request for summary judgment
7 and to convert the preliminary injunction into a permanent injunction. Even if the Court
8 concludes that AAM has associational standing, AAM's claims are legally meritless, and on those
9 additional grounds, the Court should deny AAM's summary judgment motion and request to
10 convert the preliminary injunction into a permanent injunction.

11
12 Dated: November 6, 2023

13 Respectfully submitted,

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20 /s/ Erica Connolly

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CERTIFICATE OF SERVICE

Case Name: AAM v. Becerra No. 2:20-cv-01708-TLN-DB

I hereby certify that on November 6, 2023, I electronically filed the following documents with the Clerk of the Court by using the CM/ECF system:

[REDACTED] DEFENDANT'S OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND TO CONVERT PRELIMINARY INJUNCTION INTO PERMANENT INJUNCTION

I certify that **all** participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

I declare under penalty of perjury under the laws of the State of California and the United States of America the foregoing is true and correct and that this declaration was executed on November 6, 2023, at Sacramento, California.

Kristi Dykstra
Declarant



Kristi Dykstra
Signature

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